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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/719,659	11/20/2003	Tamir Ben-David	78624/JPW/BB	2380

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EXAMINER	
BOCKELMAN, MARK	

ART UNIT	PAPER NUMBER
3766	

MAIL DATE	DELIVERY MODE
10/30/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/719,659	BEN-DAVID ET AL.	
	Examiner	Art Unit	
	Mark W. Bockelman	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 June 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-8,10-43,45-48,50-75,78-80 and 119-131* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5-8,10-43,45-48,50-75,78-80 and 119-131* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3, 5-8, 10-43, 45-48, 50-75, 78-80, 86, 119-131 are rejected under 35 U.S.C. 103(a) as being unpatentable over Osorio et al 6,341,236 in view of Schroeppel et al. or vice versa.

Schroeppel teach a device to treat various stages of heart rate variability using a plurality of treatment regimens design to control the heart. Such stimulation may be neural or for tachycardia. Although not explicitly stated, it is believed the treatments will be halted one normal heart variability is achieved. Thus the examiner considers the Schroeppel device to teach the essence of the claim reverting to a statistically normal heart rate variablilty is the goal of the device. However, the examiner includes Osorio et al for its explicit teaching of currents reducing heart rate variability. To have made the reduction of heart rate variability the goal of the Schroeppel treatments an used the Osorio et al teachniques would have been obvious.

Osorio et al teach a device and method of adjusting vagus nerve stimulation via an electrode device with controller in a manner that controls heart rate variability of a heart so as to maintain a normal heart rate using a heart rate sensor. With respect to

claims 17 and 57, bsorio teach the reduction of the standard deviation (column 9 lines 30-35, 55-60), however does not specify a time window. However, with no value placed upon the time window, the examiner considers the window to be the entire operating time of the device. Thus, the Osorio et al device is adapted to reduce the standard deviation with the operating time of the device. In addition, Osorio teaches that unacceptable heart rate variability occurring during periods of stimulation can be corrected by adjusting the stimulation parameters and/or turning off stimulation (column 9:60-65). Thus to set a window for adjusting parameters and turning off the device if the adjustments would have been obvious and yielded predictable results (that is heart rate variability reduction) as now recognized as evidence of obviousness by the courts.

With respect to claims 21-26, 29-30, 61-66, 69-70, Osorio et al teach that the vagus stimulation is in the form of pulses of .02-1.5 millisecond duration and at repetition rates of 2-2500 Hz. One could separate out each pulse as a burst or non pulse (0) pulses based upon the definitions in claims 29-30 and if not inherently suggested, would be obvious to apply them in a plurality of cycles. Regarding claim 26, when adjusting based upon a standard deviation or mean IHR (features of the cardiac signal), a delay would occur from the finished calculation to the time of stimulation.

With respect to claims 36, 90-93, 103-106 Osorio et al teaches that the heart rate and heart rate variability may be adjusted (column 9 lines 50+) using the sensed IHR input and a target calculated input (a calculated mean IHR when no vagus stimulation is applied) as well as using a statistical heart rate variable standard deviation input. The heart rate during stimulation may be lowered or raised to correspond to a mean IHR

during periods of non stimulation. The device may change the heart rate variability only, when normal mean IHR is found during stimulation and/or mean IHR and heart rate may be lowered as well if it gets too high (column 9 lines 50-65).

Regarding claims 10, 50, 86, the Osorio et al device is configured to operate during period of sensed epileptic activity. Thus, it is believed that operation is intermittent between various cardiac cycles as needed or otherwise obvious.

Concerning claims 5, 6, 12-14, 52-54, the Osorio et al device is configured to treat epileptic episodes. They may occur during periods of exertion and not occur during periods of sleep. In addition, the device is configured to operate at all times and would operate during circadian rthyms, especially those associated with epileptic attacks. Thus the device inherently meets the limitations or it would have been obvious. Applicant does not specify and means of detecting such states or specify their operation only occurs within these states.

Orsorio et al teach a device and method of adjusting vagus nerve stimulation via an electrode device with controller in a manner that controls heart rate variability of a heart so as to maintain a normal heart rate using a heart rate sensor. The stimulation is primarily to treat epileptic seizures. Claims 1 and 41 recite that the control unit is adapted to drive the current amplitude with a current of about 2 to 10 milliamps. Osorio et al teach a range of applied voltages but does not teach any current values. Stroetman et al discloses in the background of his invention, the Travar paper.which describes the use of current pulses applied to the vagus nerve of amplitudes of 0-12 mA for treating epilepsy. Providing those pulse amplitudes to likewise treat epilepsy using

the Orsorio et al device would have been obvious. The device is used to maintain the natural (mean) heart rate of the patient and thus not reduce the (mean) natural (claim 4) can is used to reduce the range up heart rates and thus reduce heart rates at the upper limit of the boundaries and thus reduce upper heart rates while reducing heart rate variability. Column 9 lines 50+ describe how the device can compare mean instantaneous heart rates with and without vagus nerve stimulation so as to adjust the stimulation in a certain percentage difference occurs. Thus it is capable of not affecting mean heart rate as well as permitting some lowering or increasing thereof within acceptable boundaries. With respect to claim 33, the device appears to provide feedback that would work with unsynchronized stimulation as well as synchronized stimulation. It is noted that applicant does not recite any structure in the claims that provides for only synchronized or unsynchronized responses. Moreover, the Osorio et al disclosure is concerned with the application of stimulation in heart cycles where minimal adverse affects occur. Thus synchronizing during normal heart rates or applying unscnhronized stimulation during time of arrhythmia would be obvious. With respect to claims 35 and 75, Osorio et al teaches that the heart rate and heart rate variability may be adjusted (column 9 lines 50+) using the sensed IHR input and a target calculated input (a calculated mean IHR when no vagal simtulation is applied) as well as using a statistical heart rate variable standard deviation input. The heart rate during stimulation may be lowered or raised to correspond to a mean IHR during periods of non-stimulation. With respect to claims 3, 7-8, 15-16, 20, 38, 39, 40, 43, 47, 48, 55, 56, 59-60, 78-80, each of these claims specifies reducing heart rate variability by a specified

amount. As noted in Osorio, heart rate variability increases during increases in heart rate. In addition, the device is used to minimize the risk of cardiac arrest (column 3, lines 12-19) thus treatment would be applied during times of arrhythmia. The goal of the Osorio et al device as well as applicant's overlaps in function, that is to control heart rate variability in a manner so as to have normalized heart rate variability in conditions, i.e. heart rates, that are identical for the human patient. Thus, the Osorio et al device would be operated in the same manner as specified by applicant, that is for optimal performance. Thus, it would be obvious that Osorio et al controller overlaps or would be designed to overlap the same functions specified by applicant and thus to reduce the variability to optimal standard deviations would have been obvious. Applicant's ranges of characteristic frequency reduction are also within the range of normal human heart activity desired. With respect to claims 18-20, 58-60, the specified window times for reducing the heart rate variability. Heart rate variability may induce arrhythmia and thus reducing it as fast as possible and within applicant's time periods is well within the level of skill in the art with both desirable and predictable results.

Claims 27-28, 32, 67-68, 72, 73, 113, 116 include synchronized or unsynchronized stimulation. As noted above, the Osorio et al disclosure is concerned with the application of stimulation in heart cycles where minimal adverse affects occur (column 3 lines 12-18) Thus synchronizing during normal heart rates so as not to induce arrythmia or applying unsynchronized stimulation during times of chaotic arrhythmia would be obvious. While Orsorio et al teach the adjustment of heart rate variability during epileptic treatments, he does not teach the explicitly teach the use of an exertion sensor,

although he may use signals within an ekg to determine the onset of a seizure (column 3 lines 60-63). While these signals may be regarded as an indication of exertion, Zabara teaches a variety of sensors that may be used to initiate vagus stimulation including heart rate sensors, respiration change sensore as well as convulsion - myoclonic jerks which all provide information that is related to exertion, espe(~ially the later. To have use the exertion sensors of Zabara to initiate treatment during times body exertions that indicate the beginning of a seizure as well as to refrain treatment during time of normalcy would have been obvious to one of ordinary skill in the art. Such a modification would yield predictable results.

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark W. Bockelman whose telephone number is (571) 272-4941. The examiner can normally be reached on Monday - Friday 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on (571) 272 -4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark W Bockelman/
Primary Examiner, Art Unit 3766
October 27, 2008